REMARKS

Claims 1-5 and 17-30 are pending. Claims 1, 4, 5, 18, 19, 22 and 30 are amended herein. Claims 6-16 are cancelled. Basis for the amendments can be found in the application and claims as originally filed. No new matter is added.

Claim Rejections under 35 U.S.C. §112, first paragraph: Lack of Enablement

Claims 1-5 and 17-30 are rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Office Action alleges that the claims are directed to all amyloid conditions associated with Alzheimer's disease and all amyloid conditions associated with islet amyloid fibrils. It is further alleged that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant respectfully requests reconsideration of the rejection in view of the amendments and arguments herein.

Analysis

Applicant submits that the standard for determining whether the specification meets the enablement requirement is whether it enables any person skilled in the art to make and use the claimed subject matter without undue experimentation. *In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 1400 (Fed, Cir, 1999) (empasis added). In determining whether any experimentation is "undue," the above-noted factors are to be considered. Applying the Wands factors to the instant claims, as described in detail below, it would not require undue experimentation to practice the instantly claimed subject matter.

Scope of the claims

Claim 1 is directed to a method of treating a disease selected from Alzheimer's disease and type II diabetes, in a mammal suffering therefrom by administration to the mammal of a therapeutically effective amount of a compound described therein. Claims 2-5 and 17-30 depend from claim 1 and further define the method and the compounds used therein.

The level of skill in the art is high

The level of skill in this art is recognized to be high (see, e.g., Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int'f 1986)). In addition, the numerous articles and patents that are of record in this application that are authored by those of a high level of skill for an audience of a high level of skill further evidences the high level of skill in this art.

The amount of direction and guidance presented, teachings in the specification

As described herein, the claims are directed a method of treating Alzheimer's disease and type II diabetes, in a mammal suffering therefrom by administration to the mammal a therapeutically effective amount of a compound described therein. The specification describes on page 16, lines 15-20, that compounds described in the instantly claimed methods act to inhibit or prevent amyloid fibril formation, inhibit or prevent amyloid fibril growth, and/or cause disassembly, disruption, and/or disaggregation of preformed amyloid fibrils and amyloid protein deposits. The *in vitro* methods to measure such activity of the compounds within the scope of the instant claims are described in Examples 1 through 4, on pages 21-26 and Assay 1, on page 28. The specification on pages 28-29, also describes an *in vivo* assay (assay 2) to measure the activity of the compounds described in the instantly claimed methods and drug products against Alzheimer's disease in humans. The exemplary embodiments described in the specification demonstrate disassembly/disruption of Alzheimer's disease Aβ 1-42 fibrils, dose-dependent disassembly/disruption of Alzheimer's disease Aβ 1-40 fibrils, disaggregation of Alzheimer's disease Aβ 1-40 fibrils, dose-dependent disaggregation of Alzheimer's disease Aβ 1-40 fibrils and disassembly/disruption of islet amyloid fibrils (amylin) by several compounds within the scope of instant claims. The specification also discloses that further *in vitro* and *in vivo* assays may be used to test the compounds for their effectiveness in the treatment of Alzheimer's disease, such as those described in European Published Patent Application No. 0 659 418. Therefore, the application provides sufficient guidance for one of skill in the art to make and use the full scope of the instantly claimed subject matter.

Presence of working examples and knowledge in the art

The application provides working examples to demonstrate the instantly claimed methods of treating Alzheimer's disease and type II diabetes. Examples 1-4 in the specification illustrate:

i) disassembly/disruption of Alzheimer's disease Aβ 1-42 fibrils by the compounds used in the instantly-claimed methods and drug products,

ii) dose-dependent disassembly/disruption of Alzheimer's disease Aβ 1-40 fibrils by tannic acid and gallic acid which are within the scope of the compounds used in the instant claims,

iii) disaggregation of Alzheimer's disease Aβ 1-40 fibrils by the compounds used in the instantly-claimed methods and drug products,

iv) dose-dependent disaggregation of Alzheimer's disease Aβ 1-40 fibrils by tannic acid and gallic acid which are within the scope of the compounds used in the instant claims. The specification also provides *in vitro* and *in vivo* assays to test the compounds for their effectiveness in the treatment of Alzheimer's disease.

Further, as described in the application and known to one of skill in the art, 90% of patients with type II diabetes demonstrate deposition of amyloid fibrils in islets of Langerhans in the pancreas. As described in example 5, the compounds within the scope of the instant claims cause disassembly/disruption of islet amyloid fibrils.

Applicants respectfully submit that the conditions recited in the claims, *i.e.*, Alzheimer's disease and type II diabetes, have shared characteristics and at least one common etiology because each is associated with extracellular amyloid deposition. Enclosed herewith are copies of peer-reviewed literature publications which indicate that amyloid deposition is responsible for a variety of diseases. Prevention/ inhibition of amyloid deposition may provide clinical benefit in such diseases. For example, an article by Porat *et al.* (submitted herewith), published after the filing date of the instant application, indicates that inhibitors of amyloid fibril formation may be useful as therapeutic agents in treatment of amyloid diseases. Further, attached article by Ono *et al.*, also published after the filing date of the instant application, describes that fibril-destabilizing activity of polyphenols provides basis for development of therapeutics for Alzheimer's disease and other human amyloidosis.

Thus, amyloid deposition is known to be associated with numerous diseases, including Alzheimer's disease and type II diabetes and the compounds that prevent or inhibit the formation, deposition, accumulation, or persistence of amyloid fibrils may provide clinical benefit in these diseases.

Conclusion

As discussed above, the instant specification describes and exemplifies methods to treat Alzheimer's disease and type II diabetes. The working examples in the specification demonstrate disassembly/disruption of Alzheimer's disease Aβ 1-42 fibrils, dose-dependent disassembly/disruption of Alzheimer's disease Ab 1-40 fibrils, disaggregation of Alzheimer's

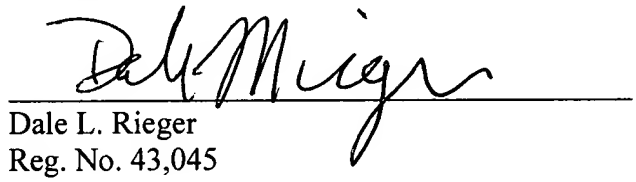
disease Aβ 1-40 fibrils, dose-dependent disaggregation of Alzheimer's disease Aβ 1-40 fibrils and disassembly/disruption of islet amyloid fibrils (amylin) by several compounds within the scope of the instant claims. Therefore, in light of the scope of the claims, the description and the working examples in the application, and the high level of skill of those in this art, it would not require undue experimentation to practice the full scope of the claims. Applicant respectfully requests reconsideration and removal of the rejection.

In view of the above, allowance of the application is respectfully requested.

Applicant hereby petitions under 37 C.F.R. §1.136 for three (3) months extension of time.

Respectfully submitted,

Date: 2/3/06



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